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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/040,103	03/17/98	MASON J	52494-21

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ESTELLE J. TSEVDOS
KENYON & KENYON
ONE BROADWAY
NEW YORK NY 10004

EXAMINER	
GUZO, D	
ART UNIT	**PAPER NUMBER**
1636	15

DATE MAILED: 05/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/040,103	Mason
Examiner	**Group Art Unit**
David Guzo	1636

☒ Responsive to communication(s) filed on *Mar 14, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-45* is/are pending in the applicat

Of the above, claim(s) *22-35, 39, and 40* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21, 36-38, and 41-45* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. This application contains claims 22-35 and 39-40 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1, 3-6, 8-11, 13-21 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Rother et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper #11) and for reasons outlined below.

Applicant traverses this rejection by asserting that Rother et al. is "generally" directed to cell lines which are of primate origin and hence outside of the claimed invention. Applicant also asserts that since Rother et al. teaches that the cell lines should be α-galactosyl negative and since the presence or absence of α-galactosyl on the cell surface is irrelevant, Rother et al. therefore

teaches away from the instant invention.

Applicant's arguments filed 3/14/00 have been fully considered but they are not persuasive.

The examiner's rejection is not predicated upon the primate cells disclosed by Rother et al. but instead the non-primate CHO and BHK cells recited by Rother et al. With regard to the presence of α-galactosyl on the cell surface, the CHO and BHK cells inherently have this molecule on the cell surface and fall within the claimed invention.

Applicant asserts that CHO and BHK cells have endogenous retrovirus sequences capable of hybridizing to a MoMLV retrovirus probe under stringent conditions. Applicant cites a reference (Lie et al.) which applicants assert shows that CHO cells have retrovirus sequences which can hybridize to MoMLV under stringent conditions. With regard to CHO cells, the examiner agrees with applicants' assertion.

However, applicant also asserts that: "BHK cells also contain endogenous retrovirus sequences which exhibit hybridization to a Moloney-MLV retrovirus probe under stringent washing conditions." (Response filed 3/14/00, p. 4). In this regard, applicant's statement is not supported by the disclosure of Lie et al. Lie et al. **did not hybridize a MoMLV probe** to BHK sequences under stringent washing conditions. Lie et al. hybridized ML2G nucleic acid probes to BHK nucleotide sequences. ML2G, while apparently related to MoMLV, exhibits significant differences in nucleotide sequence (See Lie et al., p. 7843 and Fig.3). It is further noted that Lie et al. indicates that even ML2G sequences were not detected in BHK cells but that "Extended film

exposure times did indicate that distantly related sequences exist in BHK cells (data not shown)." (p. 7845). Therefore, it must be considered that BHK cells exhibit "substantially no hybridization" to a ML2G probe since it required the exceptional added step of using extended film exposure times to show distantly related (to ML2G) sequences. In conclusion, the disclosure of Lie et al. does not provide evidence that BHK cells possess sequences that hybridize to MoMLV retrovirus probes.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 7, 12 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicant indicates that the Mpf cell line was obtained form the ATCC where it had already

been deposited and that since the cell line is publicly available from the ATCC, further deposit is unnecessary.

In response, the examiner notes that applicant is not claiming any Mpf cells but the specific Mpf cells deposited at the ATCC under Accession Number 1656-CRL. In order for the skilled artisan to practice the claimed invention, said skilled artisan would need unrestricted access to the specific Mpf cells at ATCC Accession number 1656-CRL. Applicant would have to provide a statement indicating that all restrictions on the availability of the Mpf cells would be irrevocably withdrawn upon issuance of a patent, etc. Since the Mpf cells are readily available from the ATCC and other sources, applicant is encouraged to amend the claims to delete the reference to the ATCC accession number for the Mpf cells. This would obviate the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 36-38 and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicant traverses this rejection by asserting that the phrase "…exhibits substantially no hybridization to a Moloney-MLV retrovirus probe under stringent hybridization conditions…" is clear to the skilled artisan and that said skilled artisan would known how to determine the extent of hybridization without having to resort to undue experimentation.

In response, the examiner notes that the issue is not whether undue experimentation is required to practice the claimed invention (an issue under **35 USC 112, 1st paragraph**), but the indefiniteness of the claim language under 35 USC 112, 2nd paragraph).

Applicant indicates that the phrase "substantially no hybridization" is clear to those of skill in the art. Applicant asserts that one of skill in the art would be able to distinguish between "hybridization" and "substantially no hybridization".

In response, the examiner notes that this terminology is totally unclear. The use of the term "substantially" to modify a negative or null term ("no hybridization") renders the claims containing this language unclear. If the probe does not hybridize, no hybridization is exhibited and if a probe hybridizes, then hybridization occurs. It is unclear therefore how you can have a quantity of no (zero) hybridization (i.e. **substantially no** hybridization). Either the probe hybridizes or it does not. Also, the term substantially is a subjective term with no frame of reference, i.e. "substantially" compared to what standard? How much hybridization is encompassed within the term "substantially no hybridization"? The specification is silent with regard to these issues and therefore the metes and bounds of the claimed subject matter are

unclear.

Applicant indicates that those of skill in the art can readily determine probes for use as "Moloney-MLV retrovirus probes" since the sequence of MoMLV has been known for a considerable time and preparing probes of suitable length to detect endogenous retrovirus sequences under stringent conditions is well known in the art.

In response, the examiner notes that the probe length and composition is critical in detecting whether complementary sequences are present in a sample. For example, Lie et al. notes that MoMLV and ML2G share some sequences in some regions but share little or no sequence homology is others (See Lie et al. p. 7843). Therefore, probes selected from regions of the MoMLV genome which share little or no sequence homology with ML2G (i.e. probes derived the LTR regions) would not detect the presence of this related virus in samples while probes derived from the entire MoMLV virus genome would. Since in the instant case, the skilled artisan would not know, *a priori*, what related sequences might be present in any given cellular nucleic acid sample, probe selection would greatly influence what cells would be encompassed within the claimed subject matter and therefore the length and type of probes must be specified.

Applicant indicates that the phrase "stringent conditions" is well understood by those of skill in the art and that Sambrook et al. provides ample details on determining stringency conditions required for washing the hybrids for a given probe.

In response, the examiner notes that "stringent conditions" is a subjective term with no set

definition applicable in all cases. In the instant case, the stringency of the hybridization conditions is critical in determining the metes and bounds of the cell lines encompassed within the claimed invention. Without a definition of these conditions, different cell lines would be included or excluded depending on the specific hybridization conditions chosen by the skilled artisan. Without a definitive definition of the stringent hybridization conditions used, the metes and bounds of the claimed subject matter are unclear.

With regard to applicant's arguments concerning the phrase "capable of", the examiner agrees and this part of the rejection is withdrawn.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
May 24, 2000

DAVID GUZO
PRIMARY EXAMINER